

**§ 411.350 Scope of subpart.**

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for clinical laboratory services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered items or services under Part A or Part B report information concerning their ownership, investment, or compensation arrangements in the form, manner, and at the times specified by HCFA.

**§ 411.351 Definitions.**

As used in this subpart, unless the context indicates otherwise:

*Clinical laboratory services* means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

*Compensation arrangement* means any arrangement involving any remuneration, direct or indirect, between a phy-

sician (or a member of a physician's immediate family) and an entity.

*Direct supervision* means supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.

*Employee* means any individual who, under the usual common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed at 20 CFR 404.1007 and 26 CFR 31.3121(d)-1(c).)

*Entity* means a sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association.

*Fair market value* means the value in arm's-length transactions, consistent with the general market value. With respect to rentals or leases, *fair market value* means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee.

*Financial relationship* refers to a direct or indirect relationship between a physician (or a member of a physician's immediate family) and an entity in which the physician or family member has—

(1) An ownership or investment interest that exists in the entity through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing laboratory services; or

(2) A compensation arrangement with the entity.

*Group practice* means a group of two or more physicians, legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association, that meets the following conditions:

(1) Each physician who is a *member of the group*, as defined in this section, furnishes substantially the full range of patient care services that the physician routinely furnishes including medical care, consultation, diagnosis, and treatment through the joint use of shared office space, facilities, equipment, and personnel.

(2) Except as provided in paragraphs (2)(i) and (2)(ii) of this definition, substantially all of the patient care services of the physicians who are members of the group (that is, at least 75 percent of the total patient care services of the group practice members) are furnished through the group and billed in the name of the group and the amounts received are treated as receipts of the group. "Patient care services" are measured by the total patient care time each member spends on these services. For example, if a physician practices 40 hours a week and spends 30 hours on patient care services for a group practice, the physician has spent 75 percent of his or her time providing countable patient care services.

(i) The "substantially all" test does not apply to any group practice that is located solely in an HPSA, as defined in this section, and

(ii) For group practices located outside of an HPSA (as defined in this section) any time spent by group practice members providing services in an HPSA should not be used to calculate whether the group practice located outside the HPSA has met the "substantially all" test, regardless of whether the members' time in the HPSA is spent in a group practice, clinic, or office setting.

(3) The practice expenses and income are distributed in accordance with methods previously determined.

In the case of faculty practice plans associated with a hospital, institution of higher education, or medical school that has an approved medical residency training program in which faculty practice plan physicians perform specialty and professional services, both within and outside the faculty practice, as well as perform other tasks such as research, this definition applies only to those services that are furnished within the faculty practice plan.

*Hospital* means any separate legally organized operating entity plus any subsidiary, related, or other entities that perform services for the hospital's patients and for which the hospital bills. A "hospital" does not include entities that perform services for hospital patients "under arrangements" with the hospital.

*HPSA* means, for purposes of this regulation, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in 42 CFR part 5, appendix A, part I—Geographic Areas). In addition, with respect to dental, mental health, vision care, podiatric, and pharmacy services, an HPSA means an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for dental professionals, mental health professionals, vision care professionals, podiatric professionals, and pharmacy professionals, respectively.

*Immediate family member or member of a physician's immediate family* means husband or wife; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

*Laboratory* means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

*Members of the group* means physician partners and full-time and part-time

physician contractors and employees during the time they furnish services to patients of the group practice that are furnished through the group and are billed in the name of the group.

*Patient care services* means any tasks performed by a group practice member that address the medical needs of specific patients, regardless of whether they involve direct patient encounters. They can include, for example, the services of physicians who do not directly treat patients, time spent by a physician consulting with other physicians, or time spent reviewing laboratory tests.

*Physician incentive plan* means any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

*Plan of care* means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of items or services.

*Referral—*

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, any item or service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of laboratory services or the establishment of a plan of care by a physician that includes the provision of laboratory services.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services if—

(i) The request is part of a consultation initiated by another physician; and

(ii) The tests or services are furnished by or under the supervision of the pathologist.

*Referring physician* means a physician (or group practice) who makes a referral as defined in this section.

*Remuneration* means any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies or are used solely to order or communicate the results of tests or procedures for the entity.

(3) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the plan and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.

*Transaction* means an instance or process of two or more persons doing business. An *isolated transaction* is one involving a single payment between two or more persons. A transaction that involves long-term or installment payments is not considered an isolated transaction.

**§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.**

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician